## 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K083744

## SUBMITTER

Binax, Inc., d/b/a Inverness Medical
10 Southgate Road
Scarborough, Maine 04074
(207) 730-5750 (General)
(207) 730-5717 (FAX)
Establishment Registration Number: 1221359

SEP - 1 2009

## CONTACT PERSON

Anne Jepson
anne.jepson@invmed.com (email)

## DATE PREPARED

December 12, 2008

## TRADE NAME

BinaxNOW® Malaria Positive Control

## COMMON NAMES

BinaxNOW® Malaria Positive Control, Binax NOW® Malaria Positive Control, NOW® Malaria Positive Control

## CLASSIFICATION NAME

Quality control material (assayed and unassayed), (per 21 CFR 862.1660)

## PREDICATE DEVICE

Bio-Rad Laboratories (Blackhawk BioSystems, Inc.) CryptoTrol™, 510k exempt

## DEVICE DESCRIPTION

The BinaxNOW® Malaria Positive Control is a recombinant antigen control containing a mixture of HRP II (histidine-rich protein II), which is specific for *Plasmodium falciparum* (P.f.), and a pan-malarial protein. The source of the cloned nucleic acid regions was *Plasmodium falciparum* DNA. The BinaxNOW® Malaria Positive Control can be used as a quality control sample representative of a positive test result and to verify proper performance of the procedure and reagents of the BinaxNOW® Malaria test, when it is used in accordance with the BinaxNOW® Malaria test product instructions.

The BinaxNOW® Malaria Positive Control is supplied lyophilized and is reconstituted using deionized water. The reconstituted control is then added to a pool of presumed negative EDTA human whole blood for use in the BinaxNOW® Malaria Test. When run on the BinaxNOW® Malaria Test, the positive control should always generate positive results on both the P.f. specific (HRP II) test line and on the pan malarial test line. This demonstrates that the test reagents are working as expected and that the operator performed the test procedure correctly.

**INTENDED USE**

The BinaxNOW® Malaria Positive Control is intended for use as an assayed positive external quality control with the qualitative BinaxNOW® Malaria Test. It is designed for routine use to aid in verifying proper performance of the procedure and the antigen detection reagents of the BinaxNOW® Malaria Test.

**TECHNOLOGICAL CHARACTERISTICS COMPARED TO PREDICATE DEVICE**

The BinaxNOW® Malaria Positive Control and the predicate Bio-Rad Laboratories (Blackhawk BioSystems, Inc.) CryptoTrol™ utilize different matrices and forms. The BinaxNOW® Malaria Positive Control uses recombinant malaria antigens and is supplied lyophilized, while the Bio-Rad CryptoTrol™ control utilizes purified *C. neoformans* antigens and is supplied in liquid form. Both controls are used in qualitative antigen detection tests for quality control purposes.

**PERFORMANCE SUMMARY**

Stability Studies have been performed to determine the stability and shelf life of the BinaxNOW® Malaria Positive Control in both its lyophilized (closed vial) form and its reconstituted (open vial) form. Product claims are as follows:

Lyophilized (closed vial) form: 5 months when stored at 2-8°C.

Reconstituted (open vial) form: 5 months when stored at -20°C.

Real time studies will be on-going to support and extend the shelf-life of this product.

Signed Pamela S. Angell Date 12/12/08
Pamela Angell
VP, Regulatory Affairs North America

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

Ms. Anne Jepson
Manager, Clinical Affairs
Binax, Inc.
Inverness Medical Innovations, Inc.
10 Southgate Road
Scarborough, ME 04074

SEP - 1 2009

Re: k083744
Trade/Device Name: Binax NOW® Malaria Positive Control
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control Material (assayed and unassayed)
Class: Class I
Product Code: MJZ
Dated: July 30, 20095
Received: August 4, 2009

Dear Ms. Jepson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ- Division
D.O.

**INDICATIONS FOR USE STATEMENT**

510(k) Number (if known): K083744

Device Name: BinaxNOW® Malaria Positive Control

Indications for Use:

The BinaxNOW® Malaria Positive Control is intended for use as an assayed positive external quality control with the qualitative BinaxNOW® Malaria Test. It is designed for routine use to aid in verifying proper performance of the procedure and the antigen detection reagents of the BinaxNOW® Malaria Test.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

K083744